

Kaneka Group
CDMO Services

KANEKA

Biotechnology

Sophisticated leading technology and supply tough to make compound

50 years experience in small molecule field

Technology Driven Chemistry

Polymorph control
on API crystals

Synthetic technology

Flow chemistry

New technology development programs
and manufacturing support from early to
late clinical stage and commercial supply.

Customer's process development support by FTE service.

KANEKA CORPORATION

Osaka Synthetic Chemical Laboratories Inc. (OSCL)

In addition to both enzyme technology and synthetic technology developed by Kaneka over the last 5 decades, we have expanded our technology expertise to include both flow chemistry and polymorphism control. The combination of these technologies provides Kaneka with the tools to develop chemistry for a range of targets in collaboration with our customers, from research and development to commercial development.



Solution Services

Kaneka provides a variety of services focused on Process Intensification using our core technologies, including chiral transformations through biocatalysis and chemical synthesis, and Flow Chemistry. We have a proven history as a reliable partner from the early stages of pharmaceutical product development through scale-up and commercialization using these technologies to support our customers programs through every phase of the product lifecycle. Our longstanding goal at Kaneka is to continue to support our customers through innovative technology development and manufacturing.

Process Development

- API Process Development
- Process Optimization
- Scale Up Studies & Data Collection
- Analysis Methods Development (Validation)
- Impurity Profiling

**Full line services
from early clinical stage
to commercial scale**

- Enzyme screening
- Flow Reaction process development

Manufacturing

- cGMP Manufacturing
- Stable Supplies for Commercial Demand
- Validation Production
- Establishment of Cost Effective Supply Chain with Asian Partners
- Filing Support (Data Collection, Documentation)

**Over 30 years experience
in API manufacturing**

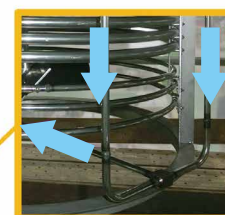
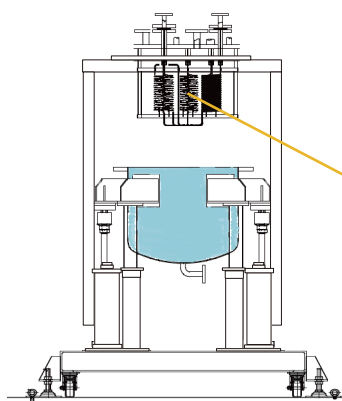
Equipment
Flow Reactors

Manufacturing Facilities

We support a wide range of production scales and various synthesis technologies.

	Kaneka Takasago	OSCL	Kaneka Singapore
Reaction Typical Scale	~10m ³	~6m ³	~20m ³
Fermenter	~250m ³	—	~40m ³
High Pressure Reactor	GL: 10m ³	SUS:1.5m ³	—
Flow Reactor	Lab scale (R&D, small scale manufacturing)	Reaction tube: ca. 0.3L (JK:100L)	Reaction tube: ca. 4L (JK:400L)
Clean rooms for APIs	—	10	—
Clean rooms for HPAPIs	—	2	—
PMDA audit	2016, July (API - intermediate)	2018, March (API)	—
FDA audit	2023, October (API)	—	2017, April (API - intermediate)

Flow Reactor



Key Technology

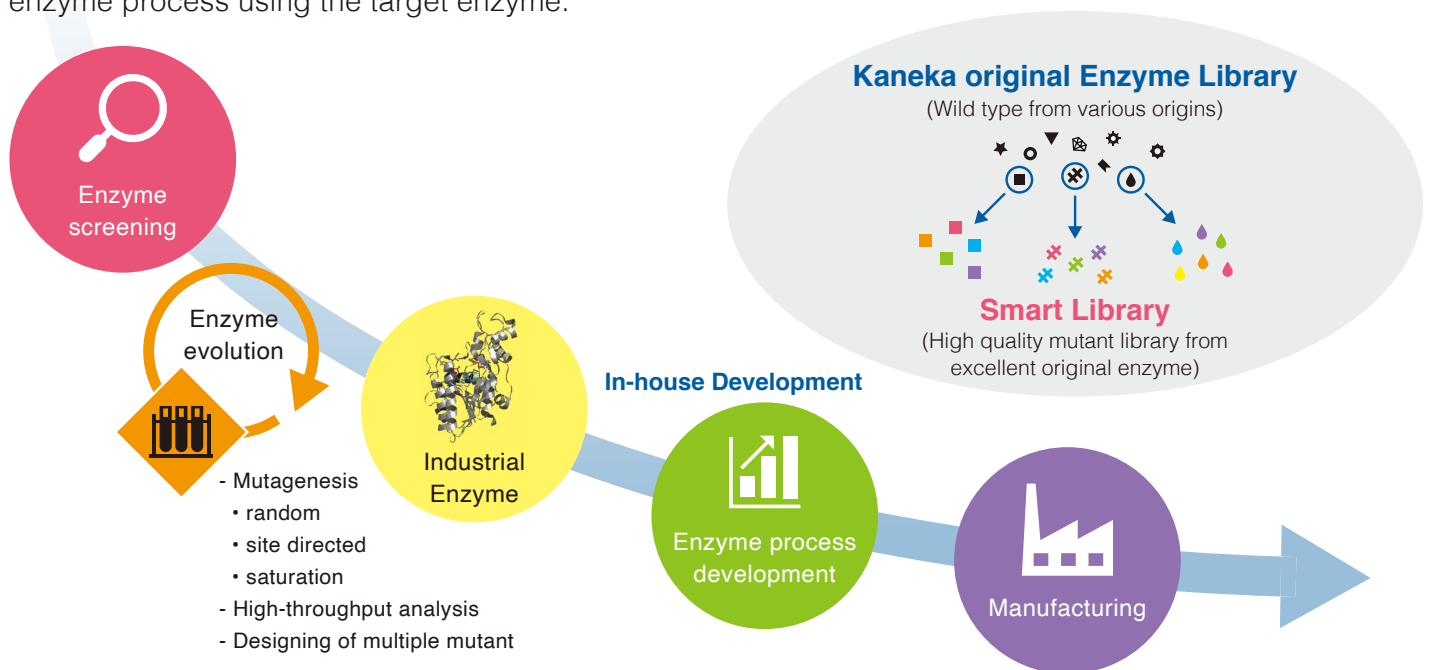
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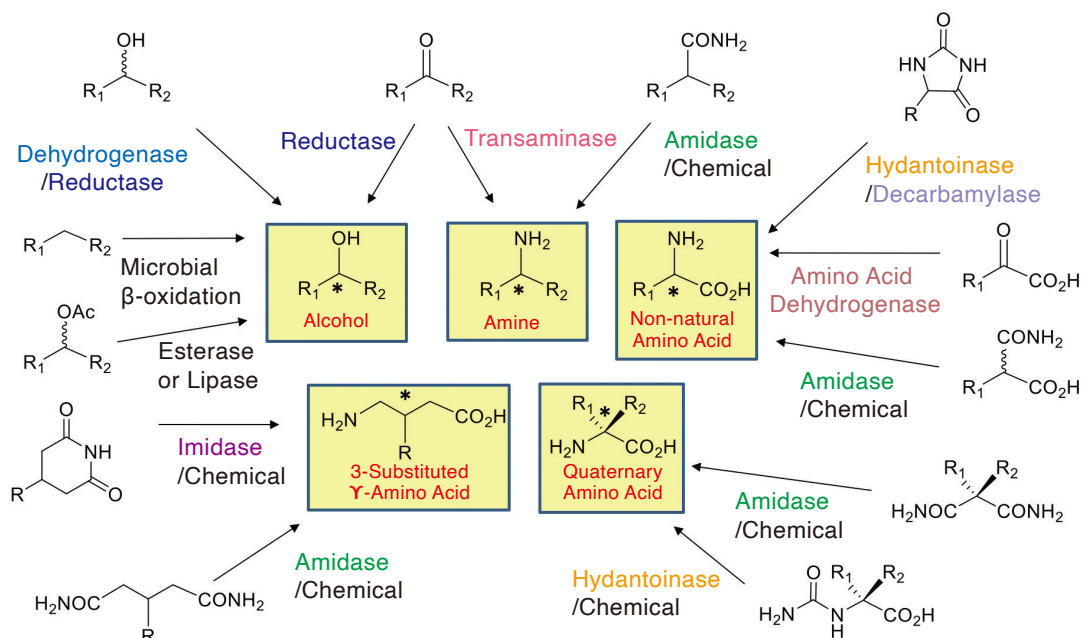
Enzyme Technology

The most proven and useful enzymes from our enzyme library form the basis of what is called the "mutant enzyme library (Smart Library) which retains enzymes that have been modified to possess a range of reactions.

We are able to carry out screening for the optimal enzyme for the customer's substrate from our original enzyme library and mutant enzyme library (Smart Library), and develop a scalable and robust enzyme process using the target enzyme.



Application examples



API Technology



Important factor of formulation

- Polymorphism control
- Particle size control (Capable of controlling particle size at 1~500 μm)

Various types of mills for APIs (Cleanrooms for exclusive use of milling are available)

Dedicated site for HPAPIs (Capable for category 4, OEL : <math><10\mu\text{g}/\text{m}^3</math>)

Flow Technology

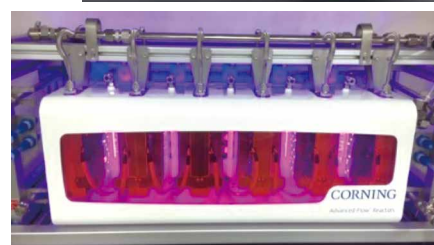


Kaneka is well positioned to utilize our continuous-flow technologies to support customer projects through the establishment and production of flow processes to support programs up to, and through commercial manufacturing and launch. This Process Intensification uses a range of Kaneka developed laboratory equipment to propose and construct the optimal continuous-flow system at both the laboratory and commercial scale. Commercial scale production can be developed using our pilot and commercial scale flow reactors, designed to directly scale the chemistry developed in our laboratories. Kaneka's flow reactors are designed to be customizable according to the characteristics of the target reaction, and are applicable to a wide range of flow reactions, including liquid-liquid, liquid-solid, and liquid-gas reactions.

Application examples

Liquid-Liquid	Lithiation, Grignard reaction, Phosgenation
Liquid-Solid	Deacylation, Asymmetric Michael reaction, Allylation
Gas-Liquid(-Solid)	Carbonylation, Hydrogenation
Photo	Halogenation, Amidation
High Temp.	Rearrangement reaction etc.

Laboratory equipment





KANEKA

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Inquiry

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